

MAR 9 2006

K053485

## 510(k) SUMMARY

**Date Summary Prepared** December 7, 2005

**Submitted by** MDS Nordion  
447 March Road  
Ottawa, Ontario K2K 1X8  
Canada  
Tel. (613) 592-3400  
Fax. (613) 592-2006

**Contact Person** Mr. Ross Kachaniwsky  
Director, Quality & Regulatory Affairs

**Device Name** Theratron Equinox 80  
Theratron Equinox 100

**Common Name** Cobalt Teletherapy Device

**Classification Name** Radionuclide Radiation Therapy System

**Legally Marketed Predicate Device** Theratron Elite 80 and 100

### Description of Device

The Theratron Equinox consists of a source head, collimator, gantry, main frame, base, controls and a pendulum or beam-stopper style counterweight. The design of this device is similar to predicate device Theratron Elite 80 and 100. For a more detailed description, please see Section 4.

### Intended Use of Device

The unit is intended to be used in:

- Delivering the intended dose at a specified position;
- Delivering the radiation in accordance with the selected relationship of the radiation to the patient (fixed or moving beam therapy, beam modifying device, etc.);
- Delivering the radiation without causing unnecessary risk to the patient, the operator, other persons, or the immediate environment.

### Summary of Technological Characteristics

The Theratron Equinox 80 and 100 is substantially equivalent to the predicate device (k983917).

The design change is to provide a new 'modern' appearance to the previous design using existing major components of the predicate device, and adds some new functionality that allows customers to treat patients with modern radiotherapy techniques while not changing the intended use of the device.

Changes include a new:

- Control System: the system is easy to maintain and diagnosis of problems is automated as much as possible
- Parameter Display: for displaying all gantry and collimator parameters relevant to treatment setup
- Control Panel: providing all hardware links to the unit that cannot be software controlled by the User Interface e.g. emergency stop
- Graphic User Interface: providing for efficient treatment setup and execution
- Hand Control – modified for modern appearance and ergonomic improvement over previous design

- Covers: The unit has a more modern appearance
- Collision Detection Device – stops motion of the gantry when a collision is detected
- Asymmetric jaws – collimator X and Y jaws can move independently
- Motorized wedge – a wedge affixed to the inside of the collimator can be moved to the in or out position
- In-room display monitors

The major components of the Theratron Elite, including the head, gantry, main frame, base, and pendulum/beam stopper counterweight have had minor modifications to accommodate the above changes.

There are no changes to the mechanical structure or radiological shielding of the head.

The irradiation source and radioactivity of the cobalt-60 source remains unchanged as does the source drawer mechanism.

The control system has been designed to meet the same intended use as the current model.

### **Safety & Effectiveness**

The safety of the Theratron Equinox 80 and 100 is equivalent or better than the predicate device.

In terms of safety, the Theratron Equinox 80 and 100 are designed to comply with

- EN 60601-1 (1995), Medical Electrical Equipment. Part 1; General requirements for safety, and
- EN 60601-1-2 (2004), Medical Electrical Equipment, Part 1; General requirements for safety; Electromagnetic Compatibility – Requirements for Tests
- EN 60601-1-4 (2001) Medical electrical equipment – Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems
- EN 60601-2-11 (2004) Medical electrical equipment – Part 2: Particular requirements for the safety of gamma beam therapy equipment
- EN 61217 (2000) Radiotherapy equipment – Coordinates, movements and scales

The performance of the device was tested against a set of functional specifications in an environment that simulated, as much as possible, the actual operating environment. Validation testing demonstrated that the device is as safe and effective as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Mr. Ross Kachaniwsky  
Director, Quality Assurance  
MDS Nordion  
447 March Road  
Ottawa, ON K2K 1X8  
CANADA

Re: K053485  
Trade/Device Name: Theratron Equinox 80  
and Theratron Equinox 100  
Regulation Number: 21 CFR 892.5750  
Regulation Name: Radionuclide radiation  
therapy system  
Regulatory Class: II  
Product Code: IWB  
Dated: February 3, 2006  
Received: February 7, 2006

Dear Mr. Kachaniwsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

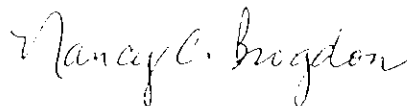
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**INDICATIONS FOR USE**

510(k) Number: K053485

Device Name:       Theratron Equinox 80  
                          Theratron Equinox 100

**Indications For Use:**

A Cobalt Teletherapy unit is a device by which gamma radiation is delivered for the treatment of cancer under the direction of health care professionals in a radiation therapy clinic.

Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

Nancy C. Brown  
Division Sign-Off)  
Division of Reproductive, Abdominal, and  
Radiological Devices  
510(k) Number K053485